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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/801,221	SANBERG ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 April 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☒ they raise the issue of new matter (see Note below);

   (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *4-20,43-61 and 70-86*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Anne-Marie Falk

Anne-Marie Falk, Ph.D.
Primary Examiner
Art Unit: 1632

Continuation Sheet (PTO-303)

Continuation of 2. NOTE:

First, the proposed amendment is improper because Claims 85 and 86 are not included in the claims listing. The claims listing must include a complete listing of all claims with the status of each claim indicated by the appropriate status identifier. See 37 CFR 1.121.

Second, the proposed claim amendments, if entered, would require multiple new grounds of rejection.

The proposed amendment raises new issues that would require further consideration and new grounds of rejection. For example, the proposed amendment to Claim 72 recites "an isolated neural cell obtained from umbilical cord blood" in place of "obtainable from" but neither the specification nor the prior art teaches a neural cell that can be obtained from umbilical cord blood. Thus, Claims 72-81 would be subject to a new ground of rejection under 35 U.S.C. 112, first paragraph, for lack of an enabling disclosure. Furthermore, the specification does not provide the necessary support for a neural cell obtained from umbilical cord blood. Thus, if entered, Claims 72-81 would be subject to a new matter rejection under 35 U.S.C. 112, first paragraph.

Continuation of 5. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

At page 12 of the response filed 4/1/04 (hereafter referred to as "the response"), Applicants assert that the specification teaches the use of the mononuclear fraction from cord blood and the use of neural cells derived therefrom for the treatment of neural damage. Applicants point to page 58 of the specification for disclosing the administration of cord blood mononuclear cells or cells that had been treated with various trophic factors prior to transplantation into rats. However, the teachings on page 58 of the specification are not commensurate in scope with the scope of the claims. The claims are directed

to methods of producing neural cells. The disclosure on page 58 of the specification states that cord blood mononuclear cells "were treated in culture for a week with various trophic factors (BDNF, NGF, EGF+bFGF)." However, the specification does not disclose the phenotype of the cells developed upon exposure to the combination of trophic factors listed, and the claims require the production of "neural cells."

At page 12, paragraph 2 of the response, Applicants refer to an experiment where human cord blood cells were proliferated and subsequently differentiated in medium containing retinoic acid and nerve growth factor (RA+NGF). Cells treated with RA+NGF yielded cells that express mRNA encoding certain neural progenitor markers as set forth at page 40 of the specification. However, the specification does not provide specific guidance teaching how to use cell compositions that have this particular gene expression profile.

At page 13, paragraph 2 of the response, Applicants argue that page 58 of the specification discusses the "results of transplantation of neural cells (HUCB cells treated with RA+NGF) into ischemic rats," and notes that the rats treated with neural cells demonstrated improved motor coordination in comparison to rats that were not treated with donor cells. However, the example described states that the cord blood mononuclear cells were "treated in culture for a week with various trophic factors (BDNF, NGF, EGF+bFGF) prior to transplantation" (p. 58, lines 7-8). Later, the example refers to "[a]nimals which received the retinoic acid + NGF treated mononuclear cells" (p. 58, line 10). Thus, it is unclear which combination of trophic factors was actually used in the experiment.

At page 13, paragraph 4 of the response, Applicants assert that they are not required to isolate and identify every neural cell that can be derived from HUCB cells. However, the specification in combination with the prior art must provide an enabling disclosure teaching how to use the full scope of the cell compositions produced according to the claimed methods. The claims are directed to methods of producing a great variety of cell compositions. The cell compositions produced according to the claimed

Continuation Sheet (PTO-303)

methods comprise a heterogeneous population of cells and the particular composition produced will depend on the particular treatment of the cells. For example, cord blood mononuclear cells treated with erythropoietin would yield a very different cell composition from cord blood mononuclear cells treated with retinoic acid. The specification does not provide an enabling disclosure teaching how to use this great variety of cell compositions, particularly in therapeutic transplantation, which is the asserted utility for the cell compositions produced according to the claimed methods.

The remainder of the arguments are directed to the claims as amended. Since the proposed amendments have not been entered for the reasons detailed above, the arguments are moot with respect to the pending claims.

Thus, the claims remain rejected for reasons of record.